

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): James B. Gibson

Application No.: 10/034,153

Filed: 12/26/2001

Title: MEDICATION ORGANIZING
SYSTEM

Attorney Docket No.: GIBSON 1

Group Art Unit: 3721

Examiner: Louis K. Huynh

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF WILLIAM E. SMITH

I, William E. Smith declare as follows:

1. I am presently Executive Associate Dean and Associate Professor at the School of Pharmacy, Virginia Commonwealth University (VCU). I have worked in the School of Pharmacy at the Virginia Commonwealth University for six years, but my experience in pharmacy and pharmacy services spans more than thirty years. For over twenty years, I was in charge of pharmacy and pharmaceutical services for a thousand bed teaching hospital in California.

2. In my experience, I have seen and attended to patients requiring multiple medications and prescriptions. Typically, elderly patients may be taking many medications at the same time. These patients may be confused or simply make mistakes with respect to taking the wrong drug or wrong dosage of drugs at the wrong times. It is recognized in the health care that


approximately 50% of patients do not comply with their prescriptions. About 20% to 25% of elderly patients hospital visits are caused by patients not taking their medications properly. Medications compliance is a serious issue. I have seen several types of medication compliance systems that attempt to address this issue.

3. I have seen a working prototype of a medication organizing system that has been presented to me by Jim Gibson. Attached is a drawing that is a reasonable representation of the system that I have been shown and that has been demonstrated to me. Also attached is a description of a system that I believe describes the prototype that Mr. Gibson has shown to me.

4. In my opinion, the medication organizing system described in the attached and that has been demonstrated to me by Mr. Gibson should be an effective system to increase medication compliance. I believe that Mr. Gibson's system is a significant improvement over medication organizing systems that are otherwise available in the market at present.

5. I declare that the foregoing statements are true and that all statements made on information and belief are believed to be true. I am aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of the application or any patent issuing thereon.

Date: 1/14/2004


William E. Smith,
Pharm.D, Ph.D, MPH

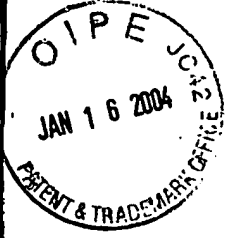
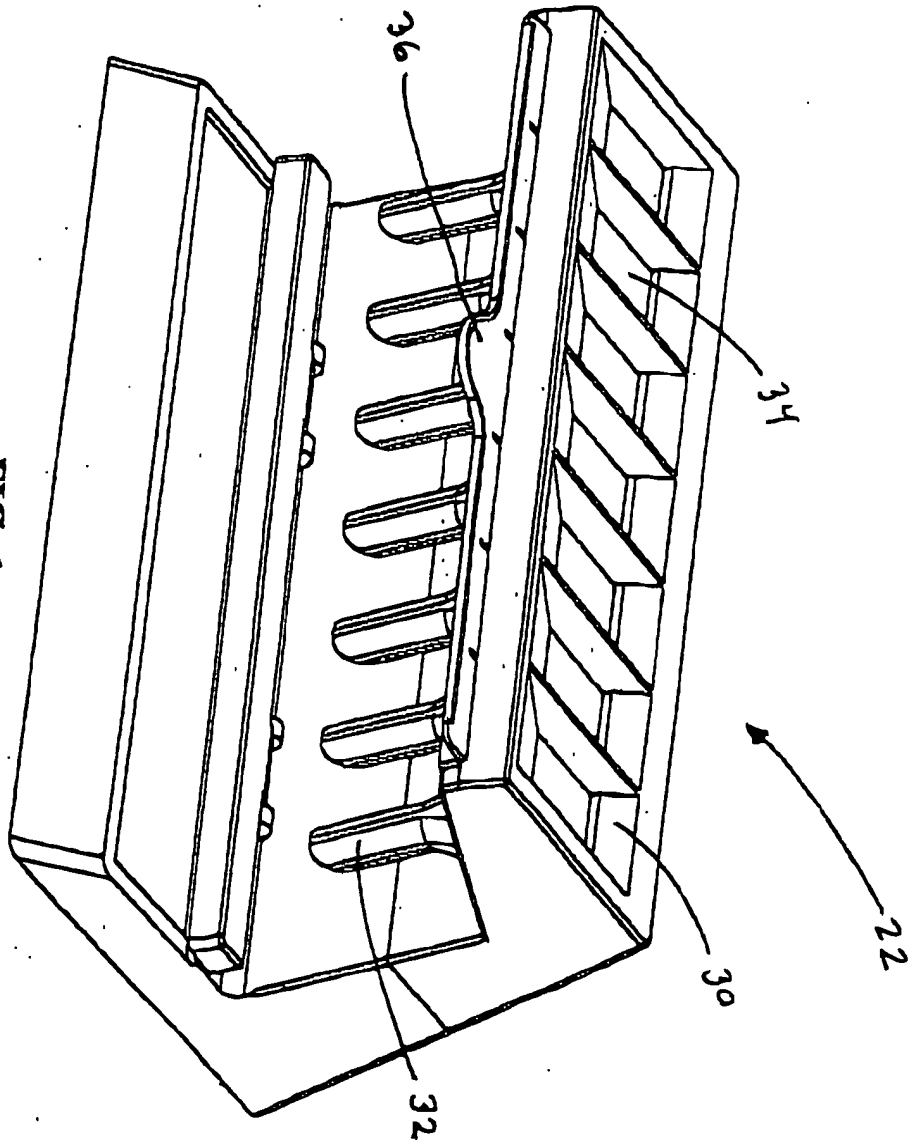
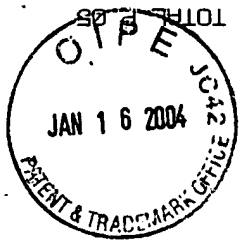


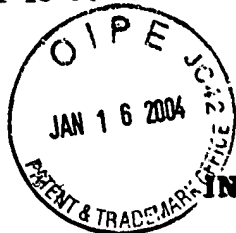
FIG. 1





1. (Twice Amended) A medication organizing system for manually preparing sealed packages of medication for daily dosages comprising:

- a plurality of hoppers in a linear arrangement;
- a plurality of nozzles, each of said nozzels associated with a corresponding one of said hoppers;
- a passageway between each of said hoppers and the associated nozzle;
- a manually operated hopper door for simultaneously opening said passageways between each of said hoppers and the associated nozzle;
- a multi-compartmented container, said multi-compartmented container comprising a plurality of bags in a linear arrangement, said bags being of a size and alignment to allow each of said bags to conform to and envelope one of said nozzels such that each of said bags can receive at least one pill from the associated hopper, and
- a heat sealing arrangement for simultaneously sealing each of said bags.

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DECLARATION OF JEFFREY C. DELAFUENTE

I, Jeffrey C. Delafuente declare as follows:

1. I am a Professor of Pharmacy and Director of Geriatric Programs at the School of Pharmacy for the Virginia Commonwealth University. I have worked at the School of Pharmacy for the past five years. I have worked in the pharmaceutical area for more than thirty years.

2. There are many problems associated with medication compliance by patients that I observed. Patients may be confused between medications in the case of multiple medications. Patients may take the wrong drugs and at the wrong times. Patients may forget to take medications when they go somewhere. It is known that 20% to 30% of hospital admissions of older patients are based on drug/medication related problems. It is also known that

for every dollar spent on drugs, more money is spent on drug related problems. There is a significant need to improve medication compliance. I have seen many types of medication compliance systems that attempt to address this issue.

3. I have seen a working prototype of a medication organizing system that has been presented to me by Jim Gibson. Attached is a drawing that is a reasonable representation of the system that I have been shown and that has been demonstrated to me. Also attached is a description of a system that I believe describes the prototype that Mr. Gibson has shown to me.

4. I believe that the medication organizing system of Mr. Gibson is going to be a significant benefit in improving medication compliance. I believe that the device is good enough and has enough promise that it is worth testing. At the School of Pharmacy, we plan to perform a test and research into the possible increased compliance in patients as a result of the use of Mr. Gibson=s device. We hope that it will reduce hospitalizations and reduce doctor visits when in use. It is also expected that Mr. Gibson=s system will help a family caregiver become involved more in the care of elder patients. We are optimistic that this is going to be an excellent tool for use by patients, especially geriatric patients.

5. I declare that the foregoing statements are true and that all statements made on information and belief are believed to be true. I am aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. ' 1001), and may jeopardize the validity of the application or any patent issuing thereon.

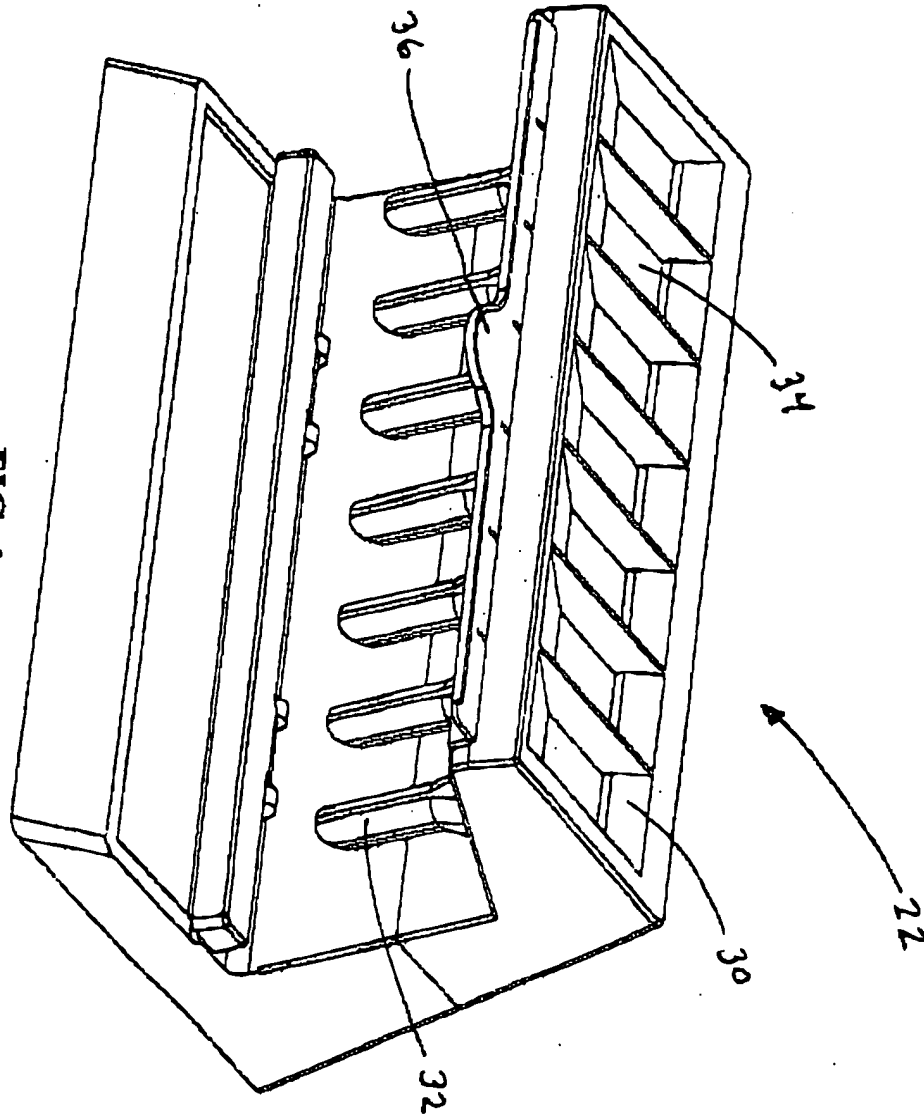
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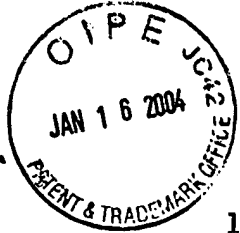
Jan 13, 2004


Jeffrey C. Delafuente



FIG. 1





1. (Twice Amended) A medication organizing system for manually preparing sealed packages of medication for daily dosages comprising:
 - a plurality of hoppers in a linear arrangement;
 - a plurality of nozzles, each of said nozzels associated with a corresponding one of said hoppers;
 - a passageway between each of said hoppers and the associated nozzle;
 - a manually operated hopper door for simultaneously opening said passageways between each of said hoppers and the associated nozzle;
 - a multi-compartmented container, said multi-compartmented container comprising a plurality of bags in a linear arrangement, said bags being of a size and alignment to allow each of said bags to conform to and envelope one of said nozzels such that each of said bags can receive at least one pill from the associated hopper, and
 - a heat sealing arrangement for simultaneously sealing each of said bags.